

# The effects of homocysteine-lowering vitamin supplementation on migraine disability

<b>Submission date</b> 29/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/12/2007	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

**Study objectives**

Does vitamin therapy including folic acid reduce homocysteine and migraine disability, and is the effect dependent on MTHFR genotype?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The study was approved by the Griffith University Ethics Committee on 11 November 2005 (ref: 3425)

### **Study design**

Randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Migraine with aura

### **Interventions**

Daily B vitamin (B6, B9, B12) therapy vs placebo for 6 months

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Migraine disability, as measured using the Migraine Disability Assessment (MIDAS) score at baseline and 6 months.

### **Key secondary outcome(s))**

1. Migraine frequency. Duration of follow-up: 6 months
2. Migraine pain: MIDAS pain score 1-10 (10 = most severe) at baseline and 6 months

### **Completion date**

30/11/2007

## **Eligibility**

### **Key inclusion criteria**

1. Current diagnosis of regular migraine with aura attacks
2. >18 and <70 years old

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Co-morbid vascular or neuropsychiatric disease
2. Pregnant
3. Currently taking B vitamins

**Date of first enrolment**

30/11/2006

**Date of final enrolment**

30/11/2007

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

**Griffith University**

Gold Coast

Australia

9726

## **Sponsor information**

**Organisation**

Griffith University (Australia)

**ROR**

<https://ror.org/02sc3r913>

# **Funder(s)**

## **Funder type**

Research organisation

## **Funder Name**

Brain Foundation of Australia

# **Results and Publications**

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Not provided at time of registration